that it is unable to collect, or to enforce collection, of a significant amount of the claim. In making this determination, HCFA will consider factors such as—

(i) Judicial remedies available;

(ii) The debtor's future financial prospects; and

(iii) Exemptions available to the debtor under State or Federal law.

(2) *Inability to locate debtor.* In cases involving missing debtors, HCFA may terminate collection action if—

(i) There is no security remaining to be liquidated;

(ii) The applicable statute of limitations has run; or

(iii) The prospects of collecting by offset, whether or not an applicable statute of limitations has run, are considered by HCFA to be too remote to justify retention of the claim.

(3) *Cost of collection exceeds recovery.* HCFA may terminate collection action if it determines that the cost of further collection action will exceed the amount recoverable.

(4) *Legal insufficiency.* HCFA may terminate collection action if it determines that the claim is legally without merit.

(5) *Evidence unavailable.* HCFA may terminate collection action if—

(i) Efforts to obtain voluntary payment are unsuccessful; and

(ii) Evidence or witnesses necessary to prove the claim are unavailable.

§ 401.623 Joint and several liability.

(a) *Collection action.* HCFA will liquidate claims as quickly as possible. In cases of joint and several liability among two or more debtors, HCFA will not allocate the burden of claims payment among the debtors. HCFA will proceed with collection action against one debtor even if other liable debtors have not paid their proportionate shares.

(b) *Compromise.* Compromise with one debtor does not release a claim against remaining debtors. Furthermore, HCFA will not consider the amount of a compromise with one debtor to be a binding precedent concerning the amounts due from other debtors who are jointly and severally liable on the claim.

§ 401.625 Effect of HCFA claims collection decisions on appeals.

Any action taken under this subpart regarding the compromise of a claim, or suspension or termination of collection action on a claim, is not an initial determination for purposes of HCFA appeal procedures.

PART 402—[RESERVED]

PART 403—SPECIAL PROGRAMS AND PROJECTS

Subpart A—[Reserved]

Subpart B—Medicare Supplemental Policies

Sec.

Subpart C—Recognition of State Reimbursement Control Systems

Subpart D—[Reserved]

Subpart E—Beneficiary Counseling and Assistance Grants

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—[Reserved]

Subpart B—Medicare Supplemental Policies

SOURCE: 47 FR 32400, July 26, 1982, unless otherwise noted.

§ 403.200 Basis and scope.

(a) *Provisions of the legislation.* This subpart implements, in part, section 1882 of the Social Security Act. The intent of that section is to enable Medicare beneficiaries to identify Medicare supplemental policies that do not duplicate Medicare, and that provide adequate, fairly priced protection against expenses not covered by Medicare. The legislation establishes certain standards for Medicare supplemental policies and provides two methods for informing Medicare beneficiaries which policies meet those standards:

(1) Through a State approved program, that is, a program that a Supplemental Health Insurance Panel determines to meet certain minimum requirements for the regulation of Medicare supplemental policies; and

(2) In a State without an approved program, through certification by the Secretary of policies voluntarily submitted by insuring organizations for review against the standards.

(b) *Scope of subpart.* This subpart sets forth the standards and procedures HCFA will use to implement the voluntary certification program.

GENERAL PROVISIONS

§ 403.201 State regulation of insurance policies.

(a) The provisions of this subpart do not affect the right of a State to regulate policies marketed in that State.

(b) Approval of a policy under the voluntary certification program, as provided for in § 403.235(b), does not authorize the insuring organization to market a policy that does not conform to applicable State laws and regulations.

§ 403.205 Medicare supplemental policy.

(a) Except as specified in paragraph (d) of this section, *Medicare supplemental policy* (policy) means a health insurance policy or other health benefit plan—

(1) That a private entity offers to a Medicare beneficiary; and

(2) That is primarily designed, or is advertised, marketed, or otherwise purported to provide payment for expenses incurred for services and items that are not reimbursed under the Medicare program because of deductibles, coinsurance, or other limitations under Medicare.

(b) Unless otherwise specified in this subpart, the term *policy* includes both policy form and policy.

(1) *Policy form* means the form of health insurance contract that is approved by and on file with the State agency for the regulation of insurance.

(2) *Policy* means the contract—

(i) Issued under the policy form; and

(ii) Held by the policyholder.

(c) Medicare supplemental policy includes the following—

(1) An individual policy.

(2) A group policy.

(d) Medicare supplemental policy does not include a Medicare+Choice plan or any of the following health insurance policies or health benefit plans:

(1) A policy or plan of one or more employers for employees, former employees, or any combination thereof.

(2) A policy or plan of one or more labor organizations for members, former members, or any combination thereof.

(3) A policy or plan of the trustees of a fund established by one or more labor organizations, one or more employers, or any combination, for any one or combination of the following—

(i) Employees.

(ii) Former employees.

(iii) Members.

(iv) Former members.

(4) A policy or plan of a profession, trade, or occupational association, if the association—

(i) Is composed of individuals all of whom are actively engaged in the same profession, trade, or occupation;

(ii) Has been maintained in good faith for a purpose other than obtaining insurance; and

(iii) Has been in existence for at least two years before the date of its initial offering of a Medicare supplemental health insurance policy to its members.

(5) For purposes of the voluntary certification program, a policy issued to an employee or to a member of a labor organization as an addition to a franchise plan (a plan that enables members of the same entity to purchase an individual policy marketed to them under group underwriting procedures), if the plan is in existence on July 1, 1982.

[47 FR 32400, July 26, 1982, as amended at 63 FR 35066, June 26, 1998]

§ 403.206 General standards for Medicare supplemental policies.

(a) For purposes of the voluntary certification program described in this subpart, a policy must meet—

(1) The National Association of Insurance Commissioners (NAIC) model standards as defined in § 405.210; and

(2) The loss ratio standards specified in § 403.215.

(b) Except as specified in paragraph (c) of this section, the standards specified in paragraph (a) of this section must be met in a single policy.

(c) In the case of a nonprofit hospital or a medical association where State law prohibits the inclusion of all benefits in a single policy, the standards specified in paragraph (a) of the section must be met in two or more policies issued in conjunction with one another.

§ 403.210 NAIC model standards.

(a) *NAIC model standards* means the National Association of Insurance Commissioners (NAIC) ''Model Regulation to Implement the Individual Accident and Insurance Minimum Standards Act'' (as amended and adopted by the NAIC on June 6, 1979, as it applies to Medicare supplemental policies). Copies of the NAIC model standards can be purchased from the National Association of Insurance Commissioners at 350 Bishops Way, Brookfield, Wisconsin 53004, and from the NIARS Corporation, 318 Franklin Avenue, Minneapolis, Minnesota 55404.

(b) The policy must comply with the provisions of the NAIC model standards, except as follows—

(1) *Policy*, for purposes of this paragraph, means individual and group policy, as specified in § 403.205. The NAIC model standards limit ''policy'' to individual policy.

(2) The policy must meet the loss ratio standards specified in § 403.215.

[47 FR 32400, July 26, 1982; 49 FR 44472, Nov. 7, 1984]

§ 403.215 Loss ratio standards.

(a) The policy must be expected to return to the policyholders, in the form of aggregate benefits provided under the policy—

(1) At least 75 percent of the aggregate amount of premiums in the case of group policies; and

(2) At least 60 percent of the aggregate amount of premiums in the case of individual policies.

(b) For purposes of loss ratio requirements, policies issued as a result of solicitation of individuals through the mail or by mass media advertising are considered individual policies.

STATE REGULATORY PROGRAMS

§ 403.220 Supplemental Health Insurance Panel.

(a) *Membership.* The Supplemental Health Insurance Panel (Panel) consists of—

(1) The Secretary or a designee, who serves as chairperson, and

(2) Four State Commissioners or Superintendents of Insurance appointed by the President. (The terms Commissioner or Superintendent of Insurance include persons of similar rank.)

(b) *Functions.* (1) The Panel determines whether or not a State regulatory program for Medicare supplemental health insurance policies meets and continues to meet minimum requirements specified in section 1882 of the Social Security Act.

(2) The chairperson of the Panel informs the State Commissioners and Superintendents of Insurance of all determinations made under paragraph (b)(1) of this section.

§ 403.222 State with an approved regulatory program.

(a) A State has an approved regulatory program if the Panel determines that the State has in effect under State law a regulatory program that provides for the application of standards, with respect to each Medicare supplemental policy issued in that State, that are equal to or more stringent than those specified in section 1882 of the Social Security Act.

(b) *Policy issued in that State* means—

(1) A group policy, if the holder of the master policy resides in that State; and

(2) An individual policy, if the policy is—

(i) Issued in that State; or

(ii) Issued for delivery in that State.

(c) A policy issued in a State with an approved regulatory program is considered to meet the NAIC model standards in § 403.210 and loss ratio standards in § 403.215.

VOLUNTARY CERTIFICATION PROGRAM: GENERAL PROVISIONS

§ 403.231 Emblem.

(a) The emblem is a graphic symbol, approved by HHS, that indicates that HCFA has certified a policy as meeting the requirements of the voluntary certification program, specified in § 403.232.

(b) Unless prohibited by the State in which the policy is marketed, the insuring organization may display the emblem on policies certified under the voluntary certification program.

(c) The manner in which the emblem may be displayed and the conditions and restrictions relating to its use will be stated in the letter with which HCFA notifies the insuring organization that a policy has been certified. The insuring organization must comply with these conditions and restrictions.

(d) If a certified policy is issued in a State that later has an approved regulatory program, as provided for in § 403.222, the insuring organization may display the emblem on the policy until the earliest of the following—

(1) When prohibited by State law or regulation.

(2) When the policy no longer meets the requirements for Medicare supplemental policies specified in § 403.206.

(3) The date the insuring organization would be required to submit material to HCFA for annual review in order to retain certification, if the State did not have an approved program (see § 403.239).

§ 403.232 Requirements and procedures for obtaining certification.

(a) To be certified by HCFA, a policy must meet—

(1) The NAIC model standards specified in § 403.210;

(2) The loss ratio standards specified in § 403.215; and

(3) Any State requirements applicable to a policy—

(i) Issued in that State; or

(ii) Marketed in that State.

(b) An insuring organization requesting certification of a policy must submit the following to HCFA for review—

(1) A copy of the policy form (including all the documents that would constitute the contract of insurance that is proposed to be marketed as a certified policy).

(2) A copy of the application form including all attachments.

(3) A copy of the uniform certificate issued under a group policy.

(4) A copy of the outline of coverage, in the form prescribed by the NAIC model standards.

(5) A copy of the Medicare supplement buyers' guide to be provided to all applicants if the buyers' guide is not the HCFA/NAIC buyers' guide.

(6) A statement of when and how the outline of coverage and the buyers' guide will be delivered and copies of applicable receipt forms.

(7) A copy of the notice of replacement and statement as to when and how that notice will be delivered.

(8) A list of States in which the policy is authorized for sale. If the policy was approved under a deemer provision in any State, the conditions involved must be specified.

(9) A copy of the loss ratio calculations, as specified in § 403.250.

(10) Loss ratio supporting data, as specified in § 403.256.

(11) A statement of actuarial opinion, as specified in § 403.258.

(12) A statement that the insuring organization will notify the policyholders in writing, within the period of time specified in § 403.245(c), if the policy is identified as a certified policy at the time of sale and later loses certification.

(13) A signed statement in which the president of the insuring organization, or a designee, attests that—

(i) The policy meets the requirements specified in paragraph (a) of this section; and

(ii) The information submitted to HCFA for review is accurate and complete and does not misrepresent any material fact.

§ 403.235 Review and certification of policies.

(a) HCFA will review policies that the insuring organization voluntarily submits, except that HCFA will not review a policy issued in a State with an approved regulatory program under § 403.222.

(b) If the requirements specified in § 403.232 are met, HCFA will—

(1) Certify the policy; and

(2) Authorize the insuring organization to display the emblem on the policy, as provided for in § 403.231.

(c) If HCFA certifies a policy, it will inform all State Commissioners and Superintendents of Insurance of that fact.

§ 403.239 Submittal of material to retain certification.

(a) HCFA certification of a policy that continues to meet the standards will remain in effect, if the insuring organization files the following material with HCFA no later than the date specified in paragraph (b) or (c) of this section—

(1) Any changes in the material, specified in § 403.232(b), that was submitted for previous certification.

(2) The loss ratio supporting data specified in § 403.256(b).

(3) A signed statement in which the president of the insuring organization, or a designee, attests that—

(i) The policy continues to meet the requirements specified in § 403.232(a); and

(ii) The information submitted to HCFA for review is accurate and complete and does not misrepresent any material fact.

(b) Except as specified in paragraph (c) of this section, the insuring organization must file the material with HCFA no later than June 30 of each year. The first time the insuring organization must file the material is no later than June 30 of the calendar year that follows the year in which HCFA—

(1) Certifies a new policy; or

(2) Certifies a policy that lost certification as provided in § 403.245.

(c) If the loss ratio calculation period, used to calculate the expected loss ratio for the last actuarial certification submitted to HCFA, ends before the June 30 date of paragraph (b) of this section, the insuring organization must file the material with HCFA no later then the last day of that rate calculation period.

§ 403.245 Loss of certification.

(a) A policy loses certification if—

(1) The insuring organization withdraws the policy from the voluntary certification program; or

(2) HCFA determines that—

(i) The policy fails to meet the requirements specified in § 403.232(a); or

(ii) The insuring organization has failed to meet the requirements for

submittal of material specified in § 403.239.

(b) If a policy loses its certification, HCFA will inform all State Commissioners and Superintendents of Insurance of that fact.

(c) If a policy that displays the emblem, or that has been marketed as a certified policy without the emblem, loses certification, the insuring organization must notify each holder of the policy, or of a certificate issued under the policy, of that fact. The notice must be in writing and sent by the earlier of—

(1) The date of the first regular premium notice after the date the policy loses its certification; or

(2) 60 days after the date the policy loses its certification.

§ 403.248 Administrative review of HCFA determinations.

(a) This section provides for administrative review if HCFA determines—

(1) Not to certify a policy; or

(2) That a policy no longer meets the standards for certification.

(b) If HCFA makes a determination specified in paragraph (a) of this section, it will send a notice to the insuring organization containing the following information:

(1) That HCFA has made such a determination.

(2) The reasons for the determination.

(3) That the insuring organization has 30 days from the date of the notice to—

(i) Request, in writing, an administrative review of the HCFA determination; and

(ii) Submit additional information to HCFA for review.

(4) That, if the insuring organization requests an administrative review, HCFA will conduct the review, as provided for in paragraph (c) of this section.

(5) That, in a case involving loss of certification, the HCFA determination will go into effect 30 days from the date of the notice, unless the insuring organization requests an administrative review. If the insuring organization requests an administrative review, the policy retains its certification until HCFA makes a final determination.

(c) If the insuring organization requests an administrative review, HCFA will conduct the review as follows—

(1) A HCFA official, not involved in the initial HCFA determination, will initiate and complete an administrative review within 90 days of the date of the notice provided for in paragraph (b) of this section.

(2) The official will consider—

(i) The original material submitted to HCFA for review, as specified in § 403.232(b) or § 403.239(a); and

(ii) Any additional information, that the insuring organization submits to HCFA.

(3) Within 15 days after the administrative review is completed, HCFA will inform the insuring organization in writing of the final decision, with an explanation of the final decision.

(4) If the final decision is that a policy lose its certification, the loss of certification will go into effect 15 days after the date of HCFA's notice informing the insuring organization of the final decision.

VOLUNTARY CERTIFICATION PROGRAM: LOSS RATIO PROVISIONS

§ 403.250 Loss ratio calculations: General provisions.

(a) *Basic formula.* The expected loss ratio is calculated by determining the ratio of benefits to premiums.

(b) *Calculations.* The insuring organization must calculate loss ratios according to the provisions of §§ 403.251, 403.253, and 403.254.

§ 403.251 Loss ratio date and time frame provisions.

(a) *Initial calculation date* means the first date of the period that the insuring organization uses to calculate the policy's expected loss ratio.

(1) The initial calculation date may be before, the same as, or after the date the insuring organization sends the policy to HCFA for review, except—

(2) The initial calculation date must not be earlier than January 1 of the calendar year in which the policy is sent to HCFA.

(b) *Loss ratio calculation period* means the period beginning with the initial calculation date and ending with the

last day of the period for which the insuring organization calculates the policy's scale of premiums.

(c) To calculate ''present values'', the insuring organization may ignore discounting (an actuarial procedure that provides for the impact of a variety of factors, such as lapse of policies) for loss ratio calculation periods not exceeding 12 months.

§ 403.253 Calculation of benefits.

(a) *General provisions.* (1) Except as provided for in paragraph (a)(2) of this section, calculate the amount of ''benefits'' by—

(i) Adding the present values on the initial calculation date of—

(A) Expected incurred benefits in the loss ratio calculation period, to—

(B) The total policy reserve at the last day of the loss ratio calculation period: and

(ii) Subtracting the total policy reserve on the initial calculation date from the sum of these values.

(2) To calculate the amount of ''benefits'' in the case of community or pool rated individual or group policies rerated on an annual basis, calculate the expected incurred benefits in the loss ratio calculation period.

(b) *Calculation of total policy reserve*—(1) *Option for calculation.* The insuring organization must calculate ''total policy reserve'' according to the provisions of paragraph (b) (2) or (3) of this section.

(2) *Total policy reserve: Federal provisions.* (i) ''Total policy reserve'' means the sum of—

(A) Additional reserve; and

(B) The reserve for future contingent benefits.

(ii) *Additional reserve* means the amount calculated on a net level reserve basis, using appropriate values to account for lapse, mortality, morbidity, and interest, that on the valuation date represents—

(A) The present value of expected incurred benefits over the loss ratio calculation period; less—

(B) The present value of expected net premiums over the loss ratio calculation period.

(iii) *Net premium* means the level portion of the gross premium used in calculating the additional reserve. On the day the policy is issued, the present value of the series of those portions equals the present value of the expected incurred claims over the period that the gross premiums are computed to provide coverage.

(iv) *Reserve for future contingent benefits* means the amounts, not elsewhere included, that provide for the extension of benefits after insurance coverage terminates. These benefits—

(A) Are predicated on a health condition existing on the date coverage ends;

(B) Accrue after the date coverage ends; and

(C) Are payable after the valuation date.

(3) *Total policy reserve: State provisions.* ''Total policy reserve'' means the total policy reserve calculated according to appropriate State law or regulation.

§ 403.254 Calculation of premiums.

(a) *General provisions.* To calculate the amount of ''premiums'', calculate the present value on the initial calculation date of expected earned premiums for the loss ratio calculation period.

(b) *Specific provisions.* (1) *Earned premium* for a given period means—

(i) Written premiums for the period; plus—

(ii) The total premium reserve at the beginning of the period; less—

(iii) The total premium reserve at the end of the period.

(2) *Written premiums in a period* means—

(i) Premiums collected in that period; plus—

(ii) Premiums due and uncollected at the end of that period; less—

(iii) Premiums due and uncollected at the beginning of that period.

(3) *Total premium reserve* means the sum of—

(i) The unearned premium reserve;

(ii) The advance premium reserve; and

(iii) The reserve for rate credits.

(4) *Unearned premium reserve* means the portion of gross premiums due that provide for days of insurance coverage after the valuation date.

(5) *Advance premium reserve* means premiums received by the insuring organization that are due after the valuation date.

(6) *Reserve for rate credits* means rate credits on a group policy that—

(i) Accrue by the valuation date of the policy; and

(ii) Are paid or credited after the valuation date.

§ 403.256 Loss ratio supporting data.

(a) For purposes of requesting HCFA certification under § 403.232, the insuring organization must submit the following loss ratio data to HCFA for review—

(1) A statement of why the policy is to be considered, for purposes of the loss ratio standards, an individual or a group policy.

(2) The earliest age at which policyholders can purchase the policy.

(3) The general marketing method and the underwriting criteria used for the selection of applicants to whom coverage is offered.

(4) What policies are to be included under the one policy form, by the dates the policies are issued.

(5) The loss ratio calculation period.

(6) The scale of premiums for the loss ratio calculation period.

(7) The expected level of earned premiums in the loss ratio calculation period.

(8) The expected level of incurred claims in the loss ratio calculation period.

(9) A description of how the following assumptions were used in calculating the loss ratio.

(i) Morbidity.

(ii) Mortality.

(iii) Lapse.

(iv) Assumed increases in the Medicare deductible.

(v) Impact of inflation on reimbursement per service.

(vi) Interest.

(vii) Expected distribution, by age and sex, of persons who will purchase the policy in the coming year.

(viii) Expected impact on morbidity by policy duration of—

(A) The process used to select insureds from among those that apply for a policy; and

(B) Pre-existing condition clauses in the policy.

(b) For purposes of requesting continued HCFA certification under § 403.239(a), the insuring organization must submit the following to HCFA—

(1) A description of all changes in the loss ratio data, specified in paragraph (a) of this section, that occurred since HCFA last reviewed the policy.

(2) The past loss ratio experience for the policy, including the experience of all riders and endorsements issued under the policy. The loss ratio experience data must include earned premiums, incurred claims, and total policy reserves that the insuring organization calculates—

(i) For all years of issue combined; and

(ii) Separately for each calendar year since HCFA first certified the policy.

§ 403.258 Statement of actuarial opinion.

(a) For purposes of certification requests submitted under § 403.232(b) and subsequent review as specified in § 403.239(a), *statement of actuarial opinion* means a signed declaration in which a qualified actuary states that the assumptions used in calculating the expected loss ratio are appropriate and reasonable, taking into account actual policy experience, if any, and reasonable expectations.

(b) *Qualified actuary* means—

(1) A member in good standing of the American Academy of Actuaries; or

(2) A person who has otherwise demonstrated his or her actuarial competence to the satisfaction of the Commissioner or Superintendent of Insurance of the domiciliary State of the insuring organization.

Subpart C—Recognition of State Reimbursement Control Systems

SOURCE: 51 FR 15492, Apr. 24, 1986, unless otherwise noted.

§ 403.300 Basis and purpose.

(a) *Basis.* This subpart implements section 1886(c) of the Act, which authorizes payment for Medicare inpatient hospital services in accordance with a State's reimbursement control system rather than under the Medicare

reimbursement principles as described in HCFA's regulations and instructions.

(b) *Purpose.* Contained in this subpart are—

(1) The basic requirements that a State reimbursement control system must meet in order to be approved by HCFA;

(2) A description of HCFA's review and evaluation procedures; and

(3) The conditions that apply if the system is approved.

§ 403.302 Definitions.

For purposes of this subpart—

Chief executive officer of a State means the Governor of the State or the Governor's designee.

Existing demonstration project refers to demonstration projects approved by HCFA under the authority of section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 (note)) and in effect on April 20, 1983 (the date of the enactment of Pub. L. 98–21 (Social Security Amendments of 1983)).

Federal hospital means a hospital that is administered by, or that is under exclusive contract with, the Department of Defense, the Veterans Administration, or the Indian Health Service.

State system or *system* refers to a State reimbursement control system that is approved by HCFA under the authority of section 1886(c) of the Act and that satisfies the requirements described in this subpart.

§ 403.304 Minimum requirements for State systems—discretionary approval.

(a) *Discretionary approval by HCFA.* HCFA may approve Medicare payments under a State system, if HCFA determines that the system meets the requirements in paragraphs (b) and (c) of this section and, if applicable paragraph (d) of this section.

(b) *Requirements for State system.* (1) An application for approval of the system must be submitted to HCFA by the Chief Executive Officer of the State.

(2) The State system must apply to substantially all non-Federal acute care hospitals in the State.

(3) All hospitals covered by the system must have and maintain a utilization and quality control review agreement with a Peer Review Organization, as required under section 1866(a)(1)(F) of the Act and § 466.78(a) of this chapter.

(4) Federal hospitals must be excluded from the State system.

(5) Nonacute care or specialty hospital (such as rehabilitation, psychiatric, or children's hospitals) may, at the option of the State, be excluded from the State system.

(6) The State system must apply to at least 75 percent of all revenues or expenses—

(i) For inpatient hospital services in the State; and

(ii) For inpatient hospital services under the State's Medicaid plan.

(7) Under the system, HMOs and competitive medical plans (CMPs), as defined by section 1876(b) of the Act and part 417 of this chapter, must be allowed to negotiate payment rates with hospitals.

(8) The system must limit hospital charges for Medicare beneficiaries to deductibles, coinsurance or non-covered services.

(9) Unless a waiver is granted by HCFA under § 489.23 of this chapter, the system must prohibit payment, as required under section 1862(a)(14) of the Act and § 405.310(m) of this chapter, for nonphysician services provided to hospital inpatients under Part B of Medicare.

(10) The system must require hospitals to submit Medicare cost reports or approved reports in lieu of Medicare cost reports as required.

(11) The system must require—

(i) Preparation, collection, or retention by the State of reports (such as financial, administrative, or statistical reports) that may be necessary, as determined by HCFA, to review and monitor the State's assurances; and

(ii) Submission of the reports to HCFA upon request.

(12) The system must provide hospitals an opportunity to appeal errors that they believe have been made in the determination of their payment rates. The system, if it is prospective may not permit providers to file administrative appeals that would result

in a retroactive revision of prospectively determined payment rates.

(c) *Satisfactory assurances.* The State must provide to HCFA satisfactory assurance as to the following:

(1) The system provides for equitable treatment of hospital patients and hospital employees.

(2) The system provides for equitable treatment of all entities that pay hospitals for inpatient hospital services, including Federal and State programs. Under the requirement, the following conditions must be met:

(i) Both the Medicare and Medicaid programs must participate under the system.

(ii) The State must assure equitable and uniform treatment under the system of third-party payors of inpatient hospital services in terms of opportunity. Equitable opportunity must include, but need not be limited to, participation in the system and availability of discounts. Criteria under which discounts are made available must be equitably and uniformly applied to all payors, except for discounts negotiated by HMOs and CMPs. Discounts available to HMOs and CMPs as result of their statutory right to negotiate payment rates independently of a State system, as described in paragraph (b)(7) of this section, need not be available to other payors.

(iii) The State must assure that all third-party payors that participate under the system share in the system's risks and benefits.

(3) The amount of Medicare payments made under the system over 36-month periods may not exceed the amount of Medicare payment that would otherwise have been made under the Medicare principles of reimbursement for Medicare items and services had the State system not been in effect. States must submit the assurance and supporting data as required by § 403.320 to document that the payment limit is not exceeded. States that have an existing Medicare demonstration project in effect on April 20, 1983, and that have requested approval of a State system under section 1886(c)(4) of the Act, may elect to have the effectiveness of the State system under this paragraph judged on the basis of the State system's rate of increase or inflation in Medicare inpatient hospital payments as compared to the national rate of increase or inflation for such payments during the three cost reporting periods of the hospitals in the State beginning on or after October 1, 1983.

(d) *Additional cost-effectiveness assurance.* If the assurances and supporting data required under paragraph (c)(3) of this section are insufficient to provide assurance satisfactory to HCFA regarding the cost-effectiveness of a State system, the State may additionally submit one of the following assurances in order to meet the cost-effectiveness test:

(1) *State responsibility for excess payments.* The State must agree that each month Medicare intermediaries will disburse to the State's hospital Federal funds that in the aggregate equal no more than would have been disbursed in the absence of the State system. Any additional funds necessary to pay hospitals for Medicare services required by the State system will be paid to the intermediaries by the State. These additional amounts will be refunded to the State by the intermediaries to the extent that, in subsequent months, the State system requires a smaller aggregate payment for Medicare services than would have been paid in the absence of the State system.

(2) *Limitations on payments.* (i) The State must agree that if its projections exceed what Medicare would pay in any particular period, the State and HCFA will establish and agreed upon payment schedule that will limit payments under the State system based on a predetermined percentage relationship between projected State payments and what payments would have been under Medicare.

(ii) If deviation from the predetermined relationship described in paragraph (d)(2)(i) of this section occurs, the State must further agree that—

(A) Medicare payments would be capped automatically at payment levels based on the rates used for the Medicare prospective payment system and the State would be required to pay the difference to individual hospitals in its system; or

(B) The State may provide by legislation or legally binding regulations that

any reduced payments to hospitals under the system that result from this cost-effectiveness assurance will constitute full and final payment for hospital services furnished to Medicare beneficiaries for the period covered by these reduced payments.

§ 403.306 Additional requirements for State systems—mandatory approval.

(a) *General policy*—(1) *Mandatory approval.* HFCA will approve an application for Medicare reimbursement under a State system if the system meets all of the requirements of § 403.304 and of paragraph (b) of this section.

(2) *Exception.* HCFA may approve an application if the State system meets all of the requirements of § 403.304 but only some of the requirements of paragraph (b) of this section.

(b) *Additional requirements*—(1) *Operation of system.* The system must—

(i) Be operated directly by the State or by entity designated under State law;

(ii) Provide for payments to hospitals using a methodology under which—

(A) Prospectively determined payment rates are established; and

(B) Exceptions, adjustments, and methods for changes in methodology are set forth;

(iii) Provide that a change by the State in the system that has the effect of materially changing payments to hospitals can take effect only upon 60 days notice to HCFA and to the hospitals likely to be materially affected by the change and upon HCFA's approval of the change.

(2) *Satisfactory assurances*—(i) *Admissions practice.* The State must assure that the operation of the system will not result in any change in hospital admission practices that result in—

(A) A significant reduction in the proportion of patients receiving hospital services covered under the system who have no third-party coverage and who are unable to pay for hospital services;

(B) A significant reduction in the proportion of individuals admitted to hospitals for inpatient hospital services for which payment is less, or is likely to be less, than the anticipated charges for or cost of the services;

(C) A refusal to admit patients who would be expected to require unusually costly or prolonged treatment for reasons other than those related to the appropriateness of the care available at the hospital; or

(D) A refusal to provide emergency services to any person who is in need of emergency services, if the hospital provides the services.

(ii) *Consultation with local government officials.* The State must provide documentation that it has consulted with local government officials concerning the impact of the system on publicly owned or operated hospitals.

§ 403.308 State systems under demonstration projects—mandatory approval.

HCFA will approve an application from a State for a State system if—

(a) The system was in effect prior to April 20, 1983 under an existing demonstration project; and

(b) The minimum requirements and assurances for approval of a State system are met under § 403.304 (b)(1)–(10) and § 403.304(c), and, if appropriate § 403.304(d).

§ 403.310 Reduction in payments.

(a) *General rule.* If HCFA determines that the satisfactory assurances required of a State under § 403.304(c) and, if applicable, § 403.304(d) have not been met, or will not be met, with respect to any 36-month period, HCFA will reduce Medicare payments to individual hospitals being reimbursed under the State's system or, if applicable, under the Medicare payment system, in an amount equal to the amount by which the Medicare payments under the system exceed the amount of Medicare payments to such hospitals that otherwise would have been made not using the State system. The amount of the recoupment will include, when appropriate, interest charges computed in accordance with § 405.378 of this chapter.

(b) *Recoupment procedures.* The amount of the overpayment will be recouped on a proportionate basis from each of those hospitals that received payments under the State system that exceeded the payments they would

have received under the Medicare payment system. Each hospital's share of the aggregate excess payment will be determined on the basis of a comparison of the hospital's proportionate share of the aggregate payment received under the State system that is in excess of what the aggregate payment would have been under the Medicare payment system. Recoupments may be accomplished by a hospital's direct payment to the Medicare program or by offsets to future payments made to the hospital.

(c) *Alternative recoupment procedures.* As an alternative to the recoupment procedures described in paragraph (b) of this section and subject to HCFA's acceptance, the State may provide, by legislation or legally binding regulations, procedures for the recoupment of the amount of payments that exceed the amount of payments that otherwise would have been paid by Medicare if the State system had not been in effect.

(d) *Rule for existing Medicare demonstration projects.* In cases of existing Medicare demonstration projects where the expenditure test is to be applied by a rate of increase factor, the amount of the excess payment will be determined, for the three hospital cost reporting periods beginning before October 1, 1986, by a comparison of the State system's rate of increase to the national rate of increase. Recoupment of excessive payments will be assessed and recouped as described in this section.

[51 FR 15492, Apr. 24, 1986, as amended at 61 FR 63748, Dec. 2, 1996]

§ 403.312 Submittal of application.

The Chief Executive Officer of the State is responsible for—

(a) Submittal of the application to HCFA for approval; and

(b) Supplying the assurances and necessary documentation as required under §§ 403.304 through 403.308.

§ 403.314 Evaluation of State systems.

HCFA will evaluate all State applications for approval of State systems and notify the State of its determination within 60 days.

§ 403.316 Reconsideration of certain denied applications.

(a) *Request for reconsideration.* If HCFA denies an application for a State system, the State may request that HCFA reconsider the denial if the State believes that its system meets all of the requirements for mandatory approval under §§ 403.304 and 403.306 or, in the case of a State with a system operating under an existing demonstration project, the applicable requirements of §§ 403.304 and 403.308.

(b) *Time limit.* (1) The State must submit its request for reconsideration within 60 days after the date of HCFA's notice that the application was denied.

(2) HCFA will notify the State of the results of its reconsideration within 60 days after it receives the request for reconsideration.

§ 403.318 Approval of State systems.

(a) *Approval agreement.* If HCFA approves a State system, a written agreement will be executed between HCFA and the Chief Executive Officer of the State. The agreement must incorporate any terms of the State's application for approval of the system as agreed to by the parties and, as a minimum, must contain provisions that require the following:

(1) The system is operated directly by the State or an entity designated by State law.

(2) For purposes of the Medicare program, the State's system applies only to Medicare payments for inpatient, and if applicable, outpatient hospital services.

(3) The system conforms to applicable Medicare law and regulations other than those relating to the amount of reimbursement for inpatient hospital services, or for inpatient and outpatient services, whichever the State system covers. Applicable regulations include, for example, those describing Medicare benefits and entitlement requirements for program beneficiaries, as explained in parts 406 and 409 of this chapter; the requirements at part 405, subpart J of this chapter specifying conditions of participation for hospitals; the requirements at part 405, subparts A, G, and S of this chapter on Medicare program administration; and

all applicable fraud and abuse regulations contained in titles 42 and 45 of the CFR.

(4) The State must obtain HCFA's approval of the State's reporting forms and of provider cost reporting forms or other forms that have not been approved by HCFA but that are necessary for the collection of required information.

(b) *Effective date.* An approved State system may not be effective earlier than the date of the approval agreement, which may not be retroactive.

§ 403.320 HCFA review and monitoring of State systems.

(a) *General rule.* The State must submit an assurance and detailed and quantitative studies of provider cost and financial data and projections to support the effectiveness of its system, as required by paragraphs (b) and (c) of this section.

(b) *Required information.* (1) Under § 403.304(c)(3) an assurance is required that the system will not result in greater payments over a 36-month period than would have otherwise been made under Medicare not using such system. If a State that has an existing demonstration project in effect on April 20, 1983 elects under § 403.304(c)(3) to have the effectiveness of its system judged on the basis of a rate of increase factor, the State must submit an assurance that its rate of increase or inflation in inpatient hospital payments does not exceed, for that portion of the 36-month period that is subject to this test, the national rate of increase or inflation in Medicare inpatient hospital payments. The election of the rate of increase test applies only to the three cost reporting periods beginning on or after October 1, 1983. At the end of these cost reporting periods, the State must assure, beginning with the first month after the expiration of the third cost reporting period beginning after October 1, 1983, that payments under its system will not exceed over the remainder of the 36-month period what Medicare payments would have been.

(2) Estimates and data are required to support the State's assurance, required under § 403.304(c)(3), that expenditures under the State system will not exceed what Medicare would have paid over a 36-month period. The estimates and projections of what Medicare would have otherwise paid must take into account all the Medicare reimbursement principles in effect at the time and, for any period in which payments either exceed or are less than Medicare levels, the values of interest the Medicare Trust Fund earned, or would have earned, on these amounts. Upon application for approval, the State must submit projections for each hospital for the first 12-month period covered by the assurance, in both the aggregate and on a per discharge basis, of Medicare inpatient expenditures under Medicare principles of reimbursement and parallel projections of Medicare inpatient expenditures under the State's system and the resulting cost or savings to Medicare. The State must also submit separate statewide projections for each year of the 36-month period, in both the aggregate and on a weighted average discharge basis, of inpatient expenditures under the State system and under the Medicare principles of reimbursement.

(3) The projection submitted under paragraph (b)(2) of this section must include a detailed description of the methodology and assumptions used to derive the expenditure amounts under both systems. In instances where the assumptions are different under the projections cited in paragraph (b)(2) of this section, the State must provide a detailed explanation of the reasons for the differences. At a minimum, the following separate data and assumptions are to be included in the projections for the Medicare principles and for the State's system.

(i) The State system base year and the Medicare allowable and reimbursable cost of each hospital that the State used to develop the projections, including the amount of estimated pass through costs.

(ii) The categories of costs that are included in the State system and are reimbursed differently under the State system than under the Medicare system.

(iii) The number of Medicare and total base year discharges and admissions for each hospital.

(iv) The rate of change factor (and the method of application of this factor) used to project the base year costs over the 36-month period to which the assurance would apply.

(v) Any allowance for anticipated growth in the amount of services from the base year (if applicable, the allowance must be presented in separate estimates for population increases or for increases in rates of admissions or both).

(vi) Any adjustment in which the State is permitted by HCFA to take into account previous reductions in the Medicare payment amounts that were the result of the effectiveness of the State's system even though Medicare was not a part of that system.

(vii) Appropriate recognition and projection of the time value of trust fund expenditures for the period the State system expenditures were either less than or exceeded the Medicare system payments.

(viii) States applying under a rate of increase effectiveness test under § 403.304(c)(3) must also submit data projecting the parallel rates of increase during the requisite period.

(4) The projections must include both the aggregate payments and the payments per discharge for the individual hospitals and for the State as a whole.

(5) On a case-by-case basis. HCFA may require additional data and documentation as needed to complete its review and monitoring.

(6) For existing Medicare demonstration projects in effect on April 20, 1983, the assurance and data as required by paragraphs (a) and (b) of this section, if appropriate, may be based on aggregate payments or payments per inpatient admission or discharge. HCFA will judge the effectiveness of these systems on the basis of the rate of increase or inflation in Medicare inpatient hospital payments compared to the national rate of increase or inflation for such payments during the State's hospitals' three cost reporting periods beginning on or after October 1, 1983. The data submitted by the State for the period subject to the rate of increase test must include the rate of increase projection for that particular period of time. For the subsequent period of time, the State must assure that payments under its system will not exceed what Medicare payments would have been, as described in § 403.304(c)(3).

(7) If the amount of Medicare payments under the State system exceeds what would have been paid under the Medicare reimbursement principles in any given year, the State must also submit quantitative evidence that the system will result in expenditures that do not exceed what Medicare expenditures would have been over the 36 month period beginning with the first month that the State system is operating. For a State that has an existing demonstration project in effect on April 20, 1983, and that elects under § 403.304(c)(3) to have a rate of increase test apply, if the State's rate of increase or inflation exceeds the national rate of increase or inflation in a given year, the State must submit quantitative evidence that, over 36 months, its payments will not exceed the national rate of increase or inflation. Furthermore, if payments under the State's system must be compared to actual Medicare expenditures, at the end of the third cost reporting period, as described in paragraph (b)(1) of this section, and payments under the State's system exceed what Medicare would have paid in a given year, the State must submit quantitative evidence that, over 36 months, payments under its system will not exceed what Medicare would have paid.

(c) *Review of assurances regarding expenditures.* HCFA will review the State's assurances and data submitted under this section, as a prerequisite to the approval of the State's system. HCFA will compare the State's projections of payment amounts to HCFA data in order to determine if the State's assurance is reasonable and fully supportable. If the HCFA data indicate that the State's system would result in payment amounts that would be more then that which would have been paid under the Medicare principles, the State's assurances would not be acceptable. For States applying in accordance with § 403.308, if HCFA data indicate that the State's system would result in a rate of increase or inflation that would be more than the national rate of increase or inflation,

the State's assurances would not be acceptable.

(d) *Medicaid upper limit.* In accordance with § 447.253 of this chapter, the State system may not result in aggregate payments for Medicaid inpatient hospital services that would exceed the amount that would have otherwise have been paid under the Medicare principles as applied through the State system.

(e) *Monitoring of Medicare expenditures.* HCFA will monitor on a quarterly basis expenditures under the State's system as compared to what Medicare expenditures would have been if the system had not been in effect. If HCFA determines at any time that the payments made under the State's system exceed the States' projections, as established by the satisfactory assurances required under § 403.304(c) and, if appropriate, the predetermined percentage relationship of the payments as required under § 403.304(d). HCFA will—

(1) Conclude that payments under the State system over a 36-month period will exceed what Medicare would have paid:

(2) Terminate the waiver; and

(3) Recoup overpayments to the affected hospitals in accordance with the procedures described in § 403.310.

§ 403.321 State systems for hospital outpatient services.

HCFA may approve a State's application for approval of an outpatient system if the following conditions are met:

(a) The State's inpatient system is approved.

(b) The State's outpatient application meets the requirements and assurances for an inpatient system described in § 403.304 (b) and (c), and § 403.306 (b)(1) and (b)(2)(ii).

(c) The State submits a separate application that provides separate assurances and estimates and data in further support of its assurance submitted under paragraph (b)(1) of § 403.320, as follows:

(1) Upon application for approval, the State must submit estimates and data that include, but are not limited to, projections for the first 12-month period covered by the assurance for each hospital, in both the aggregate and on an average cost per service and payment basis, of Medicare outpatient expenditures under Medicare principles of reimbursement; parallel projections of Medicare outpatient expenditures under the State system; and the resulting cost or savings to Medicare independent of the State system for hospital inpatient services.

(2) The State must submit separate statewide projections for each year of the 36-month period of the aggregate outpatient expenditures for each system. The projections submitted under this paragraph must—

(i) Comply with the requirements of paragraphs (b) (3) and (5) of § 403.320 regarding a detailed description of the methodology used to derive the expenditure amounts:

(ii) Include the data and assumptions set forth in paragraphs (b)(3) (i), (ii), (iii), (iv), and (v) of § 403.320; and

(iii) Include any assumption the State has adopted for establishing the number of Medicare and total base year outpatient services for each hospital.

(3) The State must provide a detailed explanation of the reasons for any difference between the data or assumptions used for the separate projections.

§ 403.322 Termination of agreements for Medicare recognition of State systems.

(a) *Termination of agreements.* (1) HCFA may terminate any approved agreement if it finds, after the procedures described in this paragraph are followed that the State system does not satisfactorily meet the requirements of section 1886(c) of the Act or the regulations in this subpart. A termination must be effective on the last day of a calendar quarter.

(2) HCFA will give the State reasonable notice of the proposed termination of an agreement and of the reasons for the termination at least 90 days before the effective date of the termination.

(3) HCFA will give the State the opportunity to present evidence to refute the finding.

(4) HCFA will issue a final notice of termination upon a final review and determination on the State's evidence.

(b) *Termination by State.* A State may voluntarily terminate a State system

by giving HCFA notice of its intent to terminate. A termination must be effective on the last day of a calendar quarter. The State must notify HCFA of its intent to terminate at least 90 days before the effective date of the termination.

Subpart D—[Reserved]

Subpart E—Beneficiary Counseling and Assistance Grants

SOURCE: 59 FR 51128, Oct. 7, 1994, unless otherwise noted.

§ 403.500 Basis, scope, and definition.

(a) *Basis.* This subpart implements, in part, the provisions of section 4360 of Public Law 101–508 by establishing a minimum level of funding for grants made to States for the purpose of providing information, counseling, and assistance relating to obtaining adequate and appropriate health insurance coverage to individuals eligible to receive benefits under the Medicare program.

(b) *Scope of subpart.* This subpart sets forth the following:

(1) Conditions of eligibility for the grant.

(2) Minimum levels of funding for those States qualifying for the grants.

(3) Reporting requirements.

(c) *Definition.* For purposes of this subpart, the term ''State'' includes (except where otherwise indicated by the context) the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

§ 403.501 Eligibility for grants.

To be eligible for a grant under this subpart, the State must have an approved Medicare supplemental regulatory program under section 1882 of the Act and submit a timely application to HCFA that meets the requirements of—

(a) Section 4360 of Public Law 101–508 (42 USC 1395b-4);

(b) This subpart; and

(c) The applicable solicitation for grant applications issued by HCFA.

§ 403.502 Availability of grants.

HCFA awards funds to States subject to congressional appropriations of funds and, if applicable, subject to the satisfactory progress in the State's project during the preceding grant period. The criteria by which progress is evaluated and the performance standards for determining whether satisfactory progress has been made is specified in the notice of grant award sent to each State. HCFA advises each State as to when to make application and provides information as to the timing of the grant award and the duration of the grant award. HCFA also provides an estimate of the amount of funds that may be available to the State.

§ 403.504 Number and size of grants.

(a) *General.* HCFA awards the following types of grants:

(1) New program grants.

(2) Existing program enhancement grants.

(b) *Grant Award.* Each eligible State that submits an acceptable application receives a grant including a fixed amount (minimum funding level) and a variable amount.

(1) A fixed portion is awarded to States in the following amounts:

(i) Each of the 50 States, $75,000.

(ii) The District of Columbia, $75,000.

(iii) Puerto Rico, $75,000.

(iv) American Samoa, $25,000.

(v) Guam, $25,000.

(vi) The Virgin Islands, $25,000.

(2) A variable portion, which is based on the number and location of Medicare beneficiaries residing in the State is awarded to each State. The variable amount a particular State receives is determined as set forth in paragraph (c) of this section.

(c) *Calculation of variable portion of the grant.* (1) HCFA bases the variable portion of the grant on—

(i) The amount of available funds, and

(ii) A comparison of each State with the average of all of the States (except the State being compared) with respect to three factors that relate to the size of the State's Medicare population and where that population resides.

(2) The factors HCFA uses to compare States' Medicare populations comprise separate components of the variable

amount. These factors, and the extent to which they each contribute to the variable amount, are as follows:

(i) Approximately 75 percent of the variable amount is based on the number of Medicare beneficiaries living in the State as a percentage of all Medicare beneficiaries nationwide.

(ii) Approximately 10 percent of the variable amount is based on the percentage of the State's total population who are Medicare beneficiaries.

(iii) Approximately 15 percent of the variable amount is based on the percentage of the State's Medicare beneficiaries that reside in rural areas (''rural areas'' are defined as all areas not included within a Metropolitan Statistical Area).

(3) Based on the foregoing four factors (that is, the amount of available funds and the three comparative factors), HCFA determines a variable rate for each participating State for each grant period.

(d) *Submission of revised budget.* A State that receives an amount of grant funds under this subpart that differs from the amount requested in the budget submitted with its application must submit a revised budget to HCFA, along with its acceptance of the grant award, that reflects the amount awarded.

§ 403.508 Limitations.

(a) *Use of grants.* Except as specified in paragraph (b) of this section, a State that receives a grant under this subpart may use the grant for any reasonable expenses incurred in planning, developing, implementing, and/or operating the program for which the grant is made.

(b) *Maintenance of effort.* A State that receives a grant to supplement an existing program (that is, an existing program enhancement grant)—

(1) Must not use the grant to supplant funds for activities that were conducted immediately preceding the date of the initial award of a grant made under this subpart and funded through other sources (including in-kind contributions).

(2) Must maintain the activities of the program at least at the level that those activities were conducted immediately preceding the initial award of a grant made under this subpart.

§ 403.510 Reporting requirements.

A State that receives a grant under this subpart must submit at least one annual report to HCFA and any additional reports as HCFA may prescribe in the notice of grant award. HCFA advises the State of the requirements concerning the frequency, timing, and contents of reports in the notice of grant award that it sends to the State.

§ 403.512 Administration.

(a) *General.* Administration of grants will be in accordance with the provisions of this subpart, 45 CFR part 92 (''Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments''), 45 CFR 74.4, the terms of the solicitation, and the terms of the notice of grant award. Except for the minimum funding levels established by § 403.504(b)(1), in the event of conflict between a provision of the notice of grant award, any provision of the solicitation, or of any regulation enumerated in 45 CFR 74.4 or in part 92, the terms of the notice of grant award control.

(b) *Notice.* HCFA provides notice to each applicant regarding HCFA's decision on an application for grant funding under § 403.504.

(c) *Appeal.* Any applicant for a grant under this subpart has the right to appeal HCFA's determination regarding its application. Appeal procedures are governed by the regulations at 45 CFR part 16 (Procedures of the Departmental Grant Appeals Board).